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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,079	10/27/2000	Donna K. Fox	0942.4460002/RWE/BJD	7547
26111	7590	05/10/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			JOHANNSEN, DIANA B	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M.

Office Action Summary	Application No. 09/697,079	Applicant(s) FOX ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45,49 and 52-56 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 45,49 and 52-56 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is responsive to the Amendment and Reply filed January 9, 2004. Claims 59-92 have been canceled, and claims 45, 49, and 52-56 are now pending and under consideration. Applicants' arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the Applicants' amendments. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. Applicant's traversal of the withdrawal of claims 59-92 in the prior Office action is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that claims 59-92 have now been canceled; accordingly, all of the claims now pending (claims 45, 49, and 52-56) are drawn to the elected invention.

Claim Rejections - 35 USC § 103

4. Claims 45, 49, and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd (WO 96/32500 [10/1996]) in view of Sobol et al (U.S. Patent No. 5,543,296 [8/1996]) and Isner (U.S. Patent No. 5,652,225 [7/1997; effective filing date 10/1994]), for the reasons stated in the Office action of September 9, 2003.

The response traverses the rejection on the following grounds.

The response asserts that the examiner has failed to establish a *prima facie* case of obviousness. First, Applicants argue that the Todd reference “is fatally deficient as a primary reference for its failure to meet the limitations of Applicants’ claims,” noting that the examiner has admitted that the Todd reference does not disclose a composition lacking nucleic acid molecules. This argument has been thoroughly considered but is not persuasive. As the instant rejection is one of obviousness, not anticipation, there is no requirement for a single reference (and specifically the Todd reference) “to meet the limitations of Applicants’ claims;” rather, as set forth in the prior Office action, it is the combined teachings of the references that suggest the claimed invention.

The response continues that the “deficiencies in Todd are not cured by the disclosure of Sobol and Isner, which do not disclose, suggest, or otherwise contemplate the modification of the compositions of Todd in such a way as to result in the presently claimed compositions.” The response states that the “Examiner’s reliance upon Sobol *et al.* and Isner *et al.* to provide motivation to prepare the compositions of the present invention is misplaced in that it mistakenly focuses on the preparation of a ‘master mix’ of PCR reagents in both of these references.” Applicants argue that the examiner’s “focus on the preparation of a master mix” in the Sobol *et al.* and Isner references “in general loses sight of the elements of present invention as claimed.” The response notes that the claims “are not drawn to the concept of making such a ‘master mix,’ but instead to novel and nonobvious **compositions**,” and states that “What makes the present invention nonobvious are the **components** of the compositions as claimed, not whether or not they are admixed prior to use.” The response asserts that “A mixture

comprising such components simply is not disclosed or suggested in the cited references, and one of ordinary skill in the art would not have been motivated to make and use the presently claimed compositions.”

These arguments have been thoroughly considered but are not persuasive. First, it is again noted that, as was indicated in the prior Office action, both the knowledge generally available to one of ordinary skill that master mixes are typically employed when performing multiple PCR reactions in order to improve efficiency, as well as the disclosure in the Isner et al reference that the use of master mixes results in “greater accuracy and reproducibility,” would have provided motivation to one of ordinary skill to employ a master mix when setting up the reactions of Todd. It is acknowledged that because Todd does not disclose the order in which reagents are combined, Todd does not disclose a combination meeting the requirements of the claims. However, given this lack of guidance in the Todd reference with respect to the manner and order in which to combine reagents, one of ordinary skill would have relied on well-known and reliable methods – such as the use of a master mix of enzymes and buffers prepared prior to addition of the primers and templates needed for each individual amplification – for the advantages of efficiency, accuracy, and reproducibility in effecting amplification, as suggested by Sobol et al and Isner. It is acknowledged that the claims are drawn to compositions, not to a method or concept of preparing a master mix. However, because the claims are drawn to products (rather than, e.g., methods requiring a particular series of steps), the cited references and/or the knowledge generally available to one of ordinary skill must merely suggest and provide a motivation

to prepare compositions meeting the requirements of the claims; the fact that the reasons for preparing the claimed compositions relied upon by the examiner, and/or the steps required to prepare said compositions, differ from the reasons that motivated Applicant and/or the steps employed by Applicant does not alter the fact that the compositions themselves are obvious. Further, the claims are not limited to particular, specific compositions with which Applicants have demonstrated unexpected results; rather, the claims encompass any composition comprising the reagents recited therein.

The response also argues that the logic employed by the examiner would render “compositions comprising **any** combination of more than one component” obvious “if the components were mixed prior to use,” citing as an example a cell culture medium with a new combination of ingredients mixed “prior to being added to petri dishes or plates.” This argument has been thoroughly considered but is not persuasive. The motivations cited by the examiner to prepare compositions meeting the requirements of the claims are not general, and would not be applicable to, e.g., cell culture media; rather, the motivations cited are specific to compositions of a particular type, and particularly, compositions including components useful in PCR. The Todd reference discloses a method of PCR, and the use of master mixes including those components required in multiple reactions (e.g., enzymes, buffers, etc.) and excluding those components required only in specific amplifications (e.g., template and primer molecules) was extremely well known in the art and widely practiced in laboratories that conduct PCR at the time the instant invention was made. The examiner has not asserted that invention is obvious “solely because it is a combination of elements that were known in the art at

the time the invention was made;" rather, a specific motivation for preparing the compositions of the claims, drawn from the teachings of the art and the knowledge generally available to one of ordinary skill, was in fact stated in the rejection and repeated above. In particular, one would have been motivated to have prepared a master mix excluding nucleic acids and including components present in the compositions of the claims for the stated advantages of improved efficiency, accuracy, and reproducibility when practicing the methods of Todd.

5. The response further asserts that "the Examiner is attempting to use Applicants' own specification, rather than in the cited art, to find the motivation required to combine the cited reference." Again, it is noted that this is not in fact the case; the motivation for combining the references is that stated in the prior Office action and repeated above, which motivation was drawn from the teachings of the art and from the knowledge generally available to one of ordinary skill. Thus, Applicants assertion that the examiner has used improper "hindsight analysis" is simply not persuasive. Further, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The combined references of Todd, Sobol et al, and Isner suggest all the limitations of present claims 45, 49, and 52-56, and therefore this rejection is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen
Patent Examiner
May 5, 2004



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5/5/04